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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,414	04/01/2004	Wolfgang Baiker	1/1454	8843
28518 7590 04/07/2008 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P. O. BOX 368 RIDGEFIELD, CT 06877-0368				
EXAMINER				
HUI, SAN MING R				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
04/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,414

Applicant(s)

BAIKER ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicant's response filed January 29, 2008 has been entered.

Claims 8-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 14, 2007.

Claims 1-7 have been examined to the extent they read on the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al., Drugs and Aging, 2002;19(2):135-161, from IDS filed February 14, 2005, in view of US 6,054,455 ('455).

Dunn et al. teaches tamsulosin as effective in treating abacterial prostatitis (see page 152, Section 4.4). Dunn et al. also teaches that NSAIDs are useful in treating chronic abacterial prostatitis (See page 152, Section 4.4).

Dunn et al. does not expressly teach meloxicam or other NSAID recited as useful in treating abacterial prostatitis.

'455 teaches tachykinin antagonist as useful in treating various prostate conditions including chronic nonbacterial prostatitis (See the abstract). '455 also teaches secondary compounds as useful in treating chronic nonbacterial prostatitis.

Such secondary compounds may be used in combination with the tachykinin antagonist (See col. 32, lines 29-47). Within such secondary agents, tamsulosin as well as NSAIDs such as ibuprofen and meloxicam are disclosed (See col. 32, line 62; also col. 33, lines 11-19, especially line 19).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate tamsulosin and NSAIDs, especially meloxicam, together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate tamsulosin and NSAIDs, especially meloxicam, together in a single composition. Tamsulosin is known to be effective in treating abacterial prostatitis. NSAIDs are well-known as helpful to treating abacterial prostatitis according to Dunn et al. Furthermore, '455 also discloses that NSAIDs such as meloxicam, are effective in treating abacterial prostatitis. Although the invention of '455 is directed to the tachykinin antagonists treating prostate conditions, possessing the teachings of '455, one of ordinary skill in the art would readily see that numerous agents are also well-known in treating the same prostate conditions. These agents include tamsulosin and NSAIDs. Therefore, combining two agents which are known to be useful to treat abacterial prostatitis individually into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

Response to Arguments

Applicant's arguments filed January 29, 2008 averring the cited prior art's failure to teach or suggest the herein claimed actives to be used in a same composition have been fully considered but they are not persuasive. The examiner notes that the basis of the rejection resides on the fact that the herein claimed actives are individually known as effective in treating abacterial prostatitis and they are also known to be useful in combination with other actives. Therefore, absent evidence of unexpected benefits, combining two agents, which are known to be useful to treat abacterial prostatitis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)). No unexpected benefits are seen to be present in the instant case.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617

